UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,358	06/26/2003	Eduardo M. Lasalvia-Prisco	1.241.03	6124

7590 01/12/2006

MALLOY & MALLOY, P.A.
Historic Coral Way
2800 S.W. Third Avenue
Miami, FL 33129

EXAMINER	
SANG, HONG	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/607,358	LASALVIA-PRISCO, EDUARDO M.	
	Examiner	Art Unit	
	Hong Sang	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-66* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

RE: Lasalvia-Prisco

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-33, drawn to a method to elicit an effective antitumoral immune response in a patient, classified in class 424, subclass 184.1.

   II. Claims 34-59, drawn to a method to elicit an effective antitumoral immune response in a patient, classified in class 424, subclass 184.1.

   III. Claims 60-65, drawn to a method of preparation of an autologous hemoderivative composition, classified in class 530, subclass 412, for example.

   VI Claim 66, drawn to an autologous hemoderivative composition, classified in class 530, subclass 350.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method to elicit an effective antitumoral immune response (groups I and II), and the method of making an autologous hemoderivative composition (group III) are unrelated as they comprise distinct steps and utilize different products which demonstrate that

each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material or comprises different methodological steps. Moreover, the methodology and materials necessary for eliciting an immune response (groups I and II), and making an autologous hemoderivative composition (group III) differ significantly for each of the materials. For groups I and II, a patient is administered with a composition, for group III, a blood sample is obtained and used to prepare the autologous hemoderivative composition. Therefore, groups I & II and group III are distinct. Groups I and II further differ from each other in that groups I and II have different method steps. Group II recites the limitations of administering different compounds to a patient at different treatment phases, which are not required by the group I. For these reasons the Inventions I-III are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. As such, it would be burdensome to search the inventions of group I-III together.

Inventions I and II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of inducing an effective antitumoral immune response can be achieved by using purified heat shock protein–peptide complex as opposed to use an antologous hemoderivative composition.

Searching the inventions of groups I & II and IV together would impose serious search burden. The inventions of groups I & II and IV have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the composition and the methods of inducing an immune response using the composition are not coextensive. Groups I & II encompasses molecules which are claimed in terms of insulin, ascorbic acid, chemotherapeutical etc., which are not required for the search of group IV. Moreover, the search for groups I-II would require a text search for the methods. Prior art which teaches a composition would not necessarily be applicable to the method of using the composition. Moreover, even if the composition product was known, the method of using the product may be novel and unobvious in view of the preamble or active steps.

Inventions III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method for making the product can be used to isolate and purify a specific enzyme for using in an assay as opposed to being used to make an autologous hemoderivative composition.

Searching the inventions of groups III and IV together would impose serious search burden. The inventions of groups III and IV have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for

the composition and the methods of making the composition are not coextensive. The search for groups III would require a text search for the method steps. Prior art which teaches a composition would not necessarily be applicable to the method of making the composition. Moreover, even if the composition product was known, the method of making the product may be novel and unobvious in view of the preamble or active steps.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. This application contains claims directed to the following patentably distinct species of the claimed invention:

(i) indomethacin, corticoid;

(ii) insulin, DNA targeted chemotherapeutic;

(iii) cyclophosphamide, methotrexate and fluorouracil;

(iv) apoptosis, autoschizis.

While both indomethacin and corticoid can induce the synthesis of a plurality of stress shock proteins, they are structurally and functionally distinct molecules. Indomethacin is a nonsteroidal anti-inflammatory drug (NSAID), whereas corticoid is a steroid hormone.

While both insulin and DNA targeted chemotherapeutic compounds can generate the TAA, insulin, which is a hormone produced by the pancreas, and chemotherapeutic

compounds such as cyclophophamide, methotrexate and fluorouracil are structurally and functionally distinct molecules.

While cyclophosphamide, methotrexate and fluorouracil are all DNA targeted chemotherapeutical agents, they are structurally and functionally distinct, which would require separate search.

The mechanisms of cell death via apoptosis and autoschizis are distinct. The compounds used to inducing cell death via apoptosis and autoschizis are structurally and functionally distinct.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of the groups (i)-(iv) listed above for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 4, 8, 15, 22, 23 and 39 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product

claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hong Sang
Art Unit 1643
Dec. 22, 2005

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER